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**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

**IN RE: NEW ENGLAND COMPOUNDING  
PHARMACY, INC. PRODUCTS LIABILITY  
LITIGATION**

**MDL No. 1:13-md-02419**

**Hon. F. Dennis Saylor, IV**

**This Document Relates To:**

*Trope, et. al. v. New England Compounding  
Pharmacy, Inc., et. al.*, No. 13-cv-10345-FDS

**MEMORANDUM IN SUPPORT OF ALAUNUS PHARMACEUTICAL, LLC'S  
MOTION TO DISMISS FIRST AMENDED COMPLAINT FOR FAILURE TO STATE A CLAIM  
PURSUANT TO FED.R.CIV.P. 12(B)(6)**

Pursuant to Federal Rule of Civil Procedure 12(b)(6), Defendant, Alaunus Pharmaceutical, LLC ("Alaunus"), by and through its counsel, hereby submits this memorandum in support of its Motion to Dismiss the Plaintiffs' First Amended Complaint.

**I. INTRODUCTION**

Plaintiffs, Helena Trope a/k/a Linda Trope and Lawrence Trope, wife and husband (collectively the "Tropes"), bring this product liability action against Defendants, New England Compounding Pharmacy, Inc. ("NECC"), Ameridose, LLC ("Ameridose"), Medical Sales Management, Inc. ("MSM"), Alaunus, Barry J. Cadden, Lisa Cadden, and Greg Conigliaro. Plaintiffs' Amended Complaint asserts various causes of action collectively against the defendants arising out of alleged injuries suffered by Mrs. Trope from an injection of an allegedly contaminated steroid compound known as methylprednisolone sodium succinate ("MSS") that was purportedly manufactured and distributed by "Defendants NECC, Ameridose, Alaunus, and MSM," and administered by her health care provider at Sinai Hospital in Baltimore, Maryland on September 21, 2012. *See Pl. Amended Compl.*, ¶¶ 14 - 18. Plaintiffs' Complaint is in ten (10) counts: Count I – Strict Liability – Manufacturing Defect; Count II – Negligence; Count III – Negligent Misrepresentation; Count IV – Breach of

Express Warranty; Count V – Breach of Implied Warranty; Count VI – Violation of Maryland’s Consumer Protection Act; Count VII – Violation of Massachusetts Consumer Protection Act; Count VIII – Damage to the Marital Relationship; Count IX – Punitive Damages; and, Count X – Piercing the Corporate Veil. *See id.*, generally.

The MSS product, around which this litigation revolves, is an injectable steroid often used for pain management which is only available to licensed healthcare providers. On September 26, 2012, NECC initiated a nationwide recall of its methylprednisolone acetate product after the Food and Drug Administration (“FDA”) and the U.S. Centers for Disease Control and Prevention (“CDC”) investigated multiple state reports of fungal meningitis among patients whom received an epidural steroid injection from one of three lots of MPA compounded in 2012 at NECC. NECC voluntarily ceased operations, surrendered its license to the Massachusetts Board of Registration in Pharmacy on October 3, 2012, and subsequently initiated a voluntary recall of all its products including MSS. On December 21, 2012, NECC filed for bankruptcy.

On January 17, 2013, Plaintiffs filed the original complaint that commenced this action with the United States District Court for the District of Maryland based upon diversity jurisdiction pursuant to 28 U.S.C. § 1332. On February 20, 2013, Plaintiffs filed with the district court for the District of Maryland a motion for leave to file a first amended complaint which is identical in all respects to the original complaint except for the substitution of Medical Sales Management, Inc. in lieu of Medical Sales Management, SW Inc. (hereinafter the “Amended Complaint”). That motion was not opposed by any of the defendants. This action was transferred to the District of Massachusetts pursuant to Conditional Transfer Order No. 1 of the Joint Panel on Multi-District Litigation and 28 U.S.C. §1407 on February 22, 2013.

Plaintiffs’ Amended Complaint should be dismissed as to Alaunus, pursuant to Fed.R.Civ.P. 12(b)(6), for many reasons. The Amended Complaint does not plead sufficient facts to show that Alaunus is jointly or vicariously liable for NECC’s alleged tortious conduct under an alter-ego liability theory. The Amended Complaint impermissibly “lumps” NECC, Ameridose, MSM, and Alaunus together. The Amended Complaint does not identify Alaunus as the manufacturer or seller of the MSS product that was used by Mrs. Trope. The negligent misrepresentation claim fails because the Amended Complaint does not show that Alaunus made any representations to the Mrs. Trope or that she relied on any such representations. The claim for breach of express

warranty fails because the Amended Complaint does not show that Alaunus extended any warranty to Mrs. Trope, that such warranty became part of the basis of the bargain or that she suffered an injury as a result of the non-conformance of any warranty extended by Alaunus. The Consumer Protection Act claims fail because MSS is not a “consumer good” within the meaning of Maryland’s Consumer Protection Act, the Amended Complaint does not show that Alaunus committed any unfair or deceptive act or practice, or that Mrs. Trope suffered an injury or loss as a result of any such conduct. Mr. Trope’s claim for “damage to the marital relationship” fails because that claim is derived from his spouse’s failed claims against Alaunus. Finally, the claim for punitive damages should be dismissed because all of the underlying tort claims against Alaunus are subject to dismissal and that the Amended Complaint does not support a plausible inference that Alaunus acted with “actual malice.”

## **II. FACTUAL ALLEGATIONS IN THE AMENDED COMPLAINT**

The Amended Complaint asserts that “NECC, [Ameridose], [Alaunus], and [MSM] are each corporations which mix, compound, manufacture, test, produce, oversee, sell and/or supply chemical compounds including methylprednisolone sodium succinate a/k/a solumedrol which was to be injected into patients, such as Linda Trope, for purposes of treatment,” and that “Defendants NECC, Ameridose, Alaunus and MSM sold and/or distributed chemical compounds which were ultimately distributed to Ortho Maryland in Baltimore, Maryland.” *Pl. Amended Compl.*, at ¶¶ 14 – 15. The Amended Complaint asserts that “[o]n or about September 21, 2012, Plaintiff Linda Trope was injected with a compound of solumedrol (‘the product’) which was mixed, compounded, manufactured, tested, produced, overseen and/or supplied by NECC, Ameridose, Alaunus and MSM,” and that, in the following days, Mrs. Trope began to suffer from headaches, photophobia, fatigue, and pain and suffering. *Id.* at ¶¶ 16 – 17. Plaintiffs allege that Mrs. Trope “was admitted to Sinai Hospital in Baltimore, Maryland on or about October 10, 2012 where a diagnosis of fungal meningitis caused by steroid injection was made.” *Id.* at ¶ 18. As a result of her treatment with an anti-fungal medication called voriconazole, the Amended Complaint asserts that “Mrs. Trope suffered acute renal disease, which further caused pain and suffering, fatigue, and damages to Mrs. Trope” and that she continues to suffer headache, photophobia, fatigue, and other pain and suffering. *Id.* at ¶¶ 19 – 21.

## **III. STANDARD OF REVIEW**

For a complaint to survive dismissal under Federal Rule of Civil Procedure 12(b)(6), it “must contain

sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). To have facial plausibility, the complaint must contain “factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S.Ct. 1937, 1949 (2009). Although the plausibility standard not akin to a probability requirement, Plaintiffs’ factual allegations must show that his claim for relief is more than “speculative” or merely “conceivable” in order to show that his claim is “plausible on its face.” *Twombly*, 550 U.S. at 555, 570 (holding that “[b]ecause the plaintiffs here have not nudged their claims across the line from conceivable to plausible, their complaint must be dismissed”). The First Circuit<sup>1</sup> has ruled that “if the factual allegations in the complaint are too meager, vague, or conclusory to remove the possibility of relief from the realm of mere conjecture, the complaint is open to dismissal.” *Plumbers’ Union Local No. 12 Pension Fund v. Nomura Asset Acceptance Corp.*, 632 F.3d 762, 771 (1st Cir. 2011).

While all *well-pled* facts contained in the complaint should be accepted by the court as true on a 12(b)(6) motion to dismiss, “a plaintiff’s obligation to provide the ‘grounds’ of [her] ‘entitle[ment] to relief’ requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” *Iqbal*, 129 S. Ct. at 1949; *Twombly*, 127 S.Ct. at 1965. Naked assertions devoid of further factual enhancement in the complaint should not be deemed as true by the court. *Maldonado v. Fontanes*, 568 F.3d 263, 266 (1st Cir. 2009).<sup>2</sup> “Conclusions” only become “facts” for pleading purposes when “conclusions are logically compelled, or at least supported, by the stated facts,” as well as the reasonable inferences drawn therefrom. *The Dartmouth Review v. Dartmouth College*, 889 F.2d 13, 16 (1st Cir. 1989).

The First Circuit has interpreted *Twombly* and *Iqbal* as requiring a two-pronged approach after the Court takes note of the elements of the claim. *Grajales v. Puerto Rico Ports Authority*, 682 F.3d 40, 44 (2012), citing

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<sup>1</sup> When a diversity action is transferred pursuant to 28 U.S.C. § 1407, the transferee court is obligated to apply federal procedural law as interpreted by the United States Court of Appeals for the First Circuit, the circuit in which this transferee court sits. See *In re Korean Air Lines Disaster of Sept. 1, 1983*, 829 F.2d 1171, 1178 (D.C. Cir. 1987), *aff’d*, 490 U.S. 122 (1989). See also *In re Donald J. Trump Casino Sec. Litig.*, 7 F.3d 357, 368 n.8 (3d Cir. 1993) (assuming without deciding that the law of the § 1407 transferee district controls federal questions); *In re Auto. Refinishing Paint*, 229 F.R.D. 482, 486-87 (E.D. Pa. 2005) (applying transferee court’s interpretation of federal law).

<sup>2</sup> See also *Barrington Cove Ltd. Partnership v. Rhode Island Housing and Mortg. Finance Corp.*, 246 F.3d 1 (1st Cir.2001) (ruling that the court should not credit “conclusory assertions, subjective characterizations, or outright vituperation”); *Aulson v. Blanchard*, 83 F.3d 1, 3 (1st Cir. 1996) (stating that the court is not obligated “to swallow the plaintiff’s invective hook, line, and sinker; bald assertions, unsupportable conclusions, periphrastic circumlocutions, and the like need not be credited”).

*Iqbal*, 556 U.S. at 678 - 679. To determine the sufficiency of a complaint under *Twombly* and *Iqbal*, the court should first “tak[e] note of the elements a plaintiff must plead to state a claim.” *Iqbal*, 129 S.Ct. at 1947, 1950. Next, “the court must separate the complaint’s factual allegations (which must be accepted as true) from its conclusory legal allegations (which need not be credited).” *Grajales*, 682 F.3d at 44, citing *Morales-Cruz v. Univ. of P.R.*, 676 F.3d 220, 224 (1st Cir.2012). Finally, the court must determine whether the factual content set forth in the complaint permits “the reasonable inference that the defendant is liable for the misconduct alleged.” *Grajales*, 682 F.3d at 44 (internal quotation marks omitted), citing *Sepúlveda-Villarini v. Dep’t of Educ. of P.R.*, 628 F.3d 25, 29 (1st Cir.2010) (Souter, J.) (“The make-or-break standard ... is that the combined allegations, taken as true, must state a plausible, not a merely conceivable, case for relief”). Where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint should be dismissed because it has alleged—but it has not “shown”—“that the pleader is entitled to relief.” *Iqbal*, 129 S.Ct. at 1950.<sup>3</sup>

#### IV. ARGUMENT

The Amended Complaint should be dismissed because Plaintiffs have not shown that Alaunus may be held liable on any theory since: (1) the pleading contains nothing but conclusory assertions of liability against Alaunus which should be ignored by the Court; and, (2) Plaintiffs have not plead facts sufficient to support the causes of action alleged.

##### 1. The Amended Complaint Contains Nothing But Conclusory Assertions Of Liability Against Alaunus Which Should Be Ignored By The Court.

The Amended Complaint does not contain any factual allegations, as opposed to conclusory assertions, supporting the conclusion that Alaunus was involved in the manufacture or sale of the product that was used by Mrs. Trope or the conclusion that Alaunus is merely an alter-ego of the co-defendants. Additionally, the pleading does not contain an adequate factual basis to distinguish the conduct of Alaunus from that of the other co-defendants. Whereas the Amended Complaint contains nothing but “naked” assertions of liability against Alaunus, such assertions should not be deemed as true by the Court and the claims against Alaunus should be dismissed pursuant to Fed.R.Civ.P. 12(b)(6).

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<sup>3</sup> There is no question that *Twombly* and *Iqbal* apply to product liability cases. See, e.g., *Lewis v. Abbot Laboratories*, No. 08 Civ. 7480, 2009 WL 2231701 (S.D.N.Y. July 24, 2009) (Depakote); *Frey v. Novartis Pharmaceuticals Corp.*, No. C-1-07-317, 2009 U.S. Dist. Lexis (S.D. Ohio July 23, 2009) (Trileptal). Further, MDL courts have had no problem applying *Twombly* and *Iqbal*. See, e.g., *In re Guidant Corp., Implantable Defibrillators*, MDL No. 05-1708, 2009 WL 1921902 (D. Minn. July 1, 2009); *In re Bausch & Lomb Inc.*, MDL No. 1785, 2007 WL 3046682 (D. S.C. 2007).

a. **The Amended Complaint Does Not Contain Any Factual Allegations Supporting The Assertion That Alaunus Was Involved In The Manufacture, Sale, Or Distribution of MSS.**

The statements in paragraphs 14 – 16 of the Amended Complaint are not “facts” which must be taken as true on a 12(b)(6) motion.

Various circuits have proposed tests for distinguishing “facts” from “conclusions” for pleading purposes. For example, in *The Dartmouth Review v. Dartmouth College*, the First Circuit stated that:

“Most often, facts are susceptible to objective verification. Conclusions, on the other hand, are empirically unverifiable in the usual case. They represent the pleader's reactions to, sometimes called 'inferences from,' the underlying facts. It is only when such conclusions are logically compelled, or at least supported, by the stated facts, that is, when the suggested inference rises to what experience indicates is an acceptable level of probability, that 'conclusions' become 'facts' for pleading purposes.”

889 F.2d 13, 16 (1st Cir. 1989). Similarly, the Third Circuit test distinguishes “facts” from “conclusions” by determining whether the statement is a pure question of fact (in which case the allegation must be accepted as true) or a pure question of law or a mixed question of fact and law (in which case the court should not accept the statement as true on a 12(b)(6) motion). *See Interfaith Cmty. Org. v. Honeywell Int’l, Inc.*, 399 F.3d 248, 269 (3rd Cir. 2005). A mixed question of fact and law can only be answered by both determining the facts of a case and determining what the relevant law means. *Id.* Applying these tests for distinguishing “facts” from “conclusions,” the courts have held that allegations involving terms that a plaintiff must prove to sustain a cause of action and which are defined by statute or common law present mixed questions of fact and law and are therefore conclusory unless supported by independent factual allegations from which an inference may be drawn to support the stated conclusion. *See DM Research v. College of American Pathologists*, 170 F. 3d 53, 55 (1st Cir. 1999) (recognizing that terms like “conspiracy” or “agreement” are conclusory unless supported by independent factual allegations in the complaint).<sup>4</sup>

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<sup>4</sup> *See also Bass v. E.I. DuPont de Nemours & Co.*, 324 F.3d 761, 765 (4th Cir. 2003) (“the words ‘hostile work environment’ are not talismanic, for they are but a legal conclusion; it is the alleged facts supporting those words, construed liberally, which are the proper focus at the motion to dismiss stage”); *Doe I v. Wal-Mart Stores, Inc.*, 572 F.3d 677, 683 (9th Cir. 2009) (holding allegation that Wal-Mart exercised “control” over day-to-day employment so as to constitute a joint employer was conclusory); *Holmes v. Poskanzer*, 342 F. App’x 651, 653 (2nd Cir. 2009) (holding that allegation that defendants were not “impartial” was conclusory and, without facts to support actual bias or conflict of interest, could not state due process claim); *TV Communications Network, Inc. v. Turner Network Television, Inc.*, 964 F.2d 1022, 1026 (10th Cir. 1992) (stating that “while TVCN uses antitrust language in its complaint, such as ‘price fixing,’ ‘group boycott’ and ‘exclusionary measures,’ it fails to elaborate on these allegations” and that “the use of antitrust ‘buzz words’ does not supply the factual circumstances necessary to support TVCN’s conclusory allegations”).

Similar to these kinds of assertions, the assertion that Alaunus and the other co-defendants are corporations “which mix, compound, manufacture, test, produce, oversee, sell and/or supply chemical compounds including [MSS], which was to be injected into patients, such as Linda Trope, for purposes of treatment,” *Pl. Amended Compl.* at ¶ 14, is not a “fact” for pleading purposes. The question of whether Alaunus may be held strictly liable for a manufacturing defect to the Plaintiffs depends, in part, on whether the Amended Complaint asserts sufficient facts to *show* that Alaunus is a “manufacturer” or “seller” within the meaning of applicable law.<sup>5</sup> Thus, the question of whether Alaunus is a “manufacturer” or “seller” is a mixed question of fact and law because it depends on an analysis of the relevant facts under applicable law to determine whether Alaunus qualifies as a party that may be held liable to the Plaintiffs. *See Ohio State Bd. of Pharmacy v. Poppe*, 48 Ohio App.3d 222, 549 N.E.2d 541 (Ohio App. 1988) (stating that “naturally, in order to determine whether a person qualifies as a ‘wholesale distributor of dangerous drugs,’ the definition of that term must be consulted” under applicable state statute).

The statement that Alaunus and the co-defendants are corporations “which mix, compound, manufacture, test, produce, oversee, sell and/or supply chemical compounds including [MSS], which was to be injected into patients, such as Linda Trope, for purposes of treatment,” *Pl. Amended Compl.* at ¶ 14, merely parrots back the definition of the term “seller” under Section 402A. The Amended Complaint does not contain any independent *factual allegations* to support the conclusion that Alaunus was a “seller” of MSS within the meaning of Section 402A. Accordingly, the statement is merely a conclusory assertion masquerading as a factual allegation which should not be taken as true on a 12(b)(6) motion. *See Iqbal*, 129 S.Ct. at 1944 (finding that Iqbal’s allegations that Ashcroft had served as the “principal architect” of a policy and that Mueller was “instrumental in adopting and executing” a policy subjecting Iqbal to harsh conditions of confinement on account of his race, religious, and national origin were merely conclusory assertions that need not be accepted as true on a 12(b)(6) motion); *In re*

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<sup>5</sup> Maryland has adopted Section 402A of the Restatement Second of Torts (1965) with regard to strict product liability claims, which contains definitions of a “seller”. *See Phipps v. General Motors Corp.*, 278 Md. 337 (1976); *Pahanish v. Western Trails, Inc.*, 69 Md. App. 342, 364 (1986). Maryland’s Code contains similar definitions of the terms “manufacturer” and “seller.” *See* MD Code, § 5-115(a)(3) (stating that the term “manufacturer” means “a designer, assembler, fabricator, constructor, compounder, producer, or processor of a product or its component parts” and includes “an individual or entity not otherwise a manufacturer that imports a product or otherwise holds itself out as a manufacturer”); MD Code, § 5-115(a)(5) (stating that the term “seller” means “a wholesaler, distributor, retailer, or other individual or entity other than a manufacturer that is regularly engaged in the selling of a product whether the sale is for resale by the purchaser or is for sale to or consumption by the ultimate consumer”).



*Fosamax Products Liability Litigation*, 2010 WL 1654156 (S.D.N.Y. April 9, 2010) (allegation that “Defendants, either directly or through [their] agents, apparent agents, servants, or employees, at all relevant times, designed, tested, developed, manufactured, labeled, marketed, distributed and sold Fosamax and Boniva” was conclusory since the complaint did not provide any specifics to support such a conclusion).<sup>6</sup>

**b. The Veil Piercing Claim Should Be Dismissed Because The Amended Complaint Asserts Only Conclusory Assertions Of Alter-Ego Liability Against Alaunus Which Should Be Ignored By The Court.**

“Under Massachusetts common law,<sup>7</sup> disregarding the corporate form is permissible only in rare situations.” *United Elec., Radio and Mach. Workers v. 163 Pleasant St. Corp. (Pleasant St. I)*, 960 F.2d 1080, 1091 (1st Cir.1992) (citing *Pepsi-Cola Metro. Bottling Co. v. Checkers, Inc.*, 754 F.2d 10, 15-16 (1st Cir.1985)). In fact, “Massachusetts has been somewhat more ‘strict’ than other jurisdictions in respecting the separate entities of different corporations.” *Birbara v. Locke*, 99 F.3d 1233, 1238 (1st Cir.1996) (quoting *My Bread Baking Co. v. Cumberland Farms, Inc.*, 353 Mass. 614, 233 N.E.2d 748, 752 (1968)) (holding that the presumption of corporate separateness may be overcome only “in rare particular situations in order to prevent gross inequity”).<sup>8</sup>

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<sup>6</sup> Even if this Court were to find that the statement in the Amended Complaint that Alaunus and the co-defendants are corporations “which mix, compound, manufacture, test, produce, oversee, sell and/or supply chemical compounds including [MSS], which was to be injected into patients, such as Linda Trope, for purposes of treatment,” is a “factual” allegation for pleading purposes (which it is not), the Court should still refuse to accept the statement as true because of the “threadbare” nature of the statement. See *Peñalbert-Rosa v. Fortuño-Burset*, 631 F.3d 592, 595 (1st Cir. 2011) (stating that “some allegations, while not stating ultimate legal conclusions, are nevertheless so threadbare or speculative that they fail to cross the line between the conclusory to the factual”).

<sup>7</sup> When a diversity action is transferred pursuant to 28 U.S.C. § 1407, the transferee court is obligated to apply the state substantive law as determined by the choice of law analysis required by the state in which the action was filed, which in this case is Maryland. See *Ferens v. John Deere Co.*, 494 U.S. 516, 524-32 (1990) (evaluating applicable law after change of venue under 28 U.S.C. § 1404(a) and holding that transferee forum was required to apply law of transferor court, regardless of which party initiated transfer); *Van Dusen v. Barrack*, 376 U.S. 612, 639 (1964) (in cases where venue was changed under 28 U.S.C. § 1404(a) the transferee district court is obligated to apply the state law that would have been applied if there had been no change of venue). When applying Maryland’s choice of law rules to veil piercing and alter ego claims, the court should look to the target entity’s state of incorporation. *Meisel v. Ustaoglu*, 2000 WL 33374486 (D. Md. 2000) (“[b]ecause Repimeks Dis is a Turkish corporation, Plaintiffs’ alter ego claims would be governed by Turkish law). Whereas the corporate defendants are all organized under Massachusetts law and have their principal place of business in this state, Massachusetts law of corporate disregard controls.

<sup>8</sup> In determining whether circumstances warrant the use of this “rare” measure, the court should undertake an inquiry into the actual nature of the corporate interrelationship to evaluate whether the “Pepsi-Cola factors” militate in favor of disregarding the corporate form. These factors are: (1) common ownership; (2) pervasive control; (3) confused intermingling of business assets; (4) thin capitalization; (5) nonobservance of corporate formalities; (6) absence of corporate records; (7) no payment of dividends; (8) insolvency at the time of the litigated transaction; (9) siphoning away of corporation’s funds by dominant shareholder; (10) nonfunctioning of officers and directors; (11) use of the corporation for transactions of the dominant shareholders; and (12) use of the corporation in promoting fraud. *Attorney Gen. v. M.C.K., Inc.*, 432 Mass. 546, n. 19 (2000) (citing *Pepsi-Cola*, 754 F.2d at 14-16).



The disregard of Alaunus' separate form is not warranted. In Count X (“Piercing the Corporate Veil”), the Amended Complaint states: (1) “[u]pon *information and belief*, Defendants Barry Cadden, Greg Conigliaro, and Lisa Cadden are shareholders of the NECC, Ameridose, Alaunus, and MSM and manage and control each and every corporate Defendant,” *Pl. Compl.* at ¶ 93; (2) “[u]pon *information and belief*, Ameridose, Alaunus, and MSM are affiliated entities of NECC, have common management with NECC, and are shareholders of NECC,” *id.* at ¶ 94; (3) “[u]pon *information and belief*, NECC fraudulently represented itself in the following ways . . .,” *id.* at ¶ 95; (4) “[u]pon *information and belief*, NECC is an undercapitalized corporation, which does not maintain control of its assets and liabilities, so that its shareholders and affiliated corporation, i.e. all co-Defendants, have allowed NECC to operate as an alter ego for their own monies,” *id.* at ¶ 96; and, (5) “[t]here is active and direct participation of NECC in the control of Alaunus, Ameridose, MSM, as well as an intermingling of activity of all corporations engaged in a common enterprise with disregard for the separate nature of the corporations. . . ,” *id.* at ¶ 97.

All of the allegations in the Amended Complaint relating to the veil piercing claim should be disregarded by the Court. Given that there are no *factual allegations of second hand information* in the Amended Complaint that supports the allegations that are made on information and belief and the other legal conclusions that are asserted in paragraphs 93 – 97 of the Amended Complaint, they are nothing more than conclusory assertions. *See Pirelli Armstrong Tire Corp. Retiree Med. Benefits Trust v. Walgreen Co.*, 631 F.3d 436, 442 (7th Cir. 2011) (when a plaintiff alleges a fact “upon information and belief,” the assertion signifies that the “allegations are based on secondhand information that [the asserting party] believes to be true”); *Zuk v. E. Pa. Psychiatric Inst. of the Med. Coll. of Pa.*, 103 F.3d 294, 299 (3d Cir. 1996) (same). Consequently, all of the allegations in paragraphs 93 – 97 of the Amended Complaint are simply conclusory assertions and a formulaic recitation of the elements of a veil piercing claim which are not entitled to the assumption of truth and should be disregarded by the Court in deciding this motion to dismiss. *See Twombly*, 127 S. Ct. at 1966 (refusing to accept conspiracy allegations, which were made on information and belief, as true because “an allegation of parallel conduct and a bare assertion of conspiracy will not suffice”).

Disregarding the conclusory assertions in paragraphs 93 – 97 of the Amended Complaint, there is no basis under *My Bread* for the disregard of the separate form of Alaunus. Even if the allegations of common ownership

and control of NECC, Ameridose, MSM, and Alaunus were deemed true for the purposes of this motion, those facts alone are not enough to warrant the disregard of Alaunus' corporate form under Massachusetts law. *See Evans v. Multicon Constr. Corp.*, 30 Mass.App.Ct. 728, rev. denied, 410 Mass. 1104, 577 N.E.2d 309 (1991) (refusing to disregard the corporate form where the only four *My Bread* factors weighed in favor of piercing included common ownership, sharing of officers and employees, exertion of pervasive control, and the shareholders' use of the corporations in aid of the transactions in which they had an interest).<sup>9</sup> Consequently, this Court should refuse to hold Alaunus vicariously liable for the alleged tortious conduct of any of the co-defendant corporate entities under a veil piercing or alter ego theory. *See Resolution Trust Corp. v. Driscoll*, 985 F.2d 44, 48 (1st Cir. 1993) (affirming dismissal of claims against corporate defendant because naked assertion of alter ego liability was not supported by sufficient factual allegations); *Griffin v. Schneider*, 995 F.2d 1061, fn. 5 (1st Cir. 1993) (where complaint alleged that defendant was the "owner" of corporate entity and "controlled its operations," First Circuit affirmed district court's dismissal of veil piercing and alter-ego claims holding that plaintiff failed to allege sufficient facts to warrant the disregard of the corporate entity's identity, the piercing of its corporate veil, or the imposition of alter ego liability on defendant).<sup>10</sup>

**c. All Counts Of The Amended Complaint Should Be Dismissed As To Alaunus Because The Pleading Impermissibly "Lumps" NECC, Ameridose, MSM, And Alaunus Together.**

The pleading rules have eschewed the "lumping" of defendants together. A complaint fails to meet the minimum standard of pleading under Fed.R.Civ.P. 8(a) where the complaint does not contain an adequate factual

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<sup>9</sup> Courts in other jurisdictions uniformly hold that common ownership, control, and management is not enough to warrant disregard of the corporate form. *See United States v. Bestfoods*, 524 U.S. 51, 69 (1998) (overlap in directors or officers among affiliated corporate entities is not unusual, and is widely held to be insufficient to establish alter ego liability alone); *Am. Protein Corp. v. AB Volvo*, 844 F.2d 56, 57 (2d Cir. 1988) (overlap in directors or officers among affiliated corporate entities is not unusual, and is widely held to be insufficient to establish alter ego liability alone); *Steven v. Roscoe Turner Aeronautical*, 324 F.2d 157, 161 (7th Cir. 1963) ("[w]hile stock control and common directors and officers are generally prerequisites for application of the instrumentality rule, yet, they are not sufficient by themselves to bring the rule into operation"); *Akzona, Inc. v. E.I. Du Pont de Nemours & Co.*, 607 F. Supp. 227, 237 (D. Del. 1984) (holding that overlapping directors was insufficient to pierce veil).

<sup>10</sup> *See also De Jesus v. Sears, Roebuck & Co.*, 87 F.3d 65, 70 (2d Cir. 1996) (granting 12(b)(6) motion to dismiss since complaint was "devoid of any specific facts or circumstances supporting" liability of an individual on a veil piercing theory); *Stanley v. Central Garden and Pet Corp*, 2012 WL 4127619 (D. Md. 2012) (applying Maryland law) (granting 12(b)(6) motion to dismiss as to veil piercing claim under *Twombly* and *Iqbal*); *Chen v. Century Buffet and Restaurant*, 2011 U.S. Dist. Lexis 43102 (D. N.J. 2011) (granting 12(b)(6) motion to dismiss for failure to plead sufficient facts to support an alter ego theory of liability); *In re Currency Conversion Fee Antitrust Litig.*, 265 F. Supp. 2d 385, 426 (S.D.N.Y. 2003) ("purely conclusory allegations cannot suffice to state a claim based on veil piercing or alter-ego liability, even under the liberal notice pleading standard").

basis to distinguish the conduct of particular defendants. *Bagheri v. Galligan*, 160 Fed. Appx. 4, 5, 2005 WL 3536555 (1<sup>st</sup> Cir. 2005) (upholding district court's dismissal of action where the original complaint did not “state clearly which defendant or defendants committed each of the alleged wrongful acts”); *Tolbert v. Clarke*, Civ. Action No. 10-11643, 2011 WL 797372 (D. Mass. 2011) (Zobel, J.) (“lumping” of all of the defendants together is impermissible when it cannot be reasonably inferred that all of the defendants were involved, or it is otherwise not clear to which defendant or defendants the plaintiff is referring).

Here, the Amended Complaint impermissibly “lumps” NECC, Ameridose, MSM, and Alaunus together. Plaintiffs’ Amended Complaint asserts that “*NECC, [Ameridose], [Alaunus], and [MSM]* are each corporations which mix, compound, manufacture, test, produce, oversee, sell and/or supply” MSS, that “*NECC, Ameridose, Alaunus and MSM* sold and/or distributed chemical compounds” which were distributed to Maryland, and that Mrs. Trope was injected with a compound of MSS “which was mixed, compounded, manufactured, tested, produced, overseen and/or supplied by *NECC, Ameridose, Alaunus and MSM.*” *Pl. Compl.* at ¶¶ 14 – 17. Aside from the veil piercing count, all of the other counts in the Amended Complaint merely refer to NECC, Ameridose, MSM, Alaunus, and the individual defendants collectively as “Defendants” and fails to plead any basis to distinguish the conduct of Alaunus from that of the other corporate and individual defendants. *See id.* at ¶¶ 22 – 91. Whereas the Amended Complaint impermissibly “lumps” Alaunus together with the other corporate and individual defendants and there is no basis to disregard the separate form of Alaunus, all counts of the Amended Complaint should be dismissed as to Alaunus under *Twombly-Iqbal* because the allegations in the pleading do not give adequate notice to Alaunus as to what it did wrong and therefore fails to meet the pleading standards of Rule 8. *See Bagheri*, 160 Fed. Appx. at 5; *Tolbert*, 2011 WL 797372 (D. Mass. 2011) (Zobel, J.).<sup>11</sup>

## 2. **The Amended Complaint Does Not Contain Sufficient Allegations To Show That Alaunus Is Liable For The Conduct Alleged.**

Turning to the causes of action asserted in the Amended Complaint, the Plaintiffs woefully fail to show

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<sup>11</sup> *See also Atuahene v. City of Hartford*, 10 Fed. Appx. 33, 34 (2<sup>nd</sup> Cir. 2001) (“by lumping all the defendants together in each claim and providing no factual basis to distinguish their conduct, [plaintiff]’s complaint failed to satisfy [the] minimum standard” of pleading under Fed.R.Civ.P. 8(a)); *Goren v. New Vision Intern., Inc.*, 156 F.3d 721, 730 (7<sup>th</sup> Cir. 1998) (affirming dismissal where complaint treated defendants as one by “lumping” them together); *Vanzandt v. OK Dep’t Human Serv’s.*, 276 Fed. Appx. 843 (10<sup>th</sup> Cir. 2008) (“to carry their burden, plaintiffs under the *Twombly* standard must do more than generally use the collective term ‘defendants.’ . . . This is because the purposes of plausibility, notice, and gatekeeping are best served by requiring plaintiffs to directly link an actual individual with the alleged improper conduct”).

that Alaunus is liable under any of the causes of action asserted in the pleading.

a. **All Counts of the Amended Complaint Should Be Dismissed Because It Does Not Show that the Alleged Defect is Attributable to Alaunus.**

Under Maryland law, the plaintiff in any products liability action, regardless of whether such action is based in strict liability, negligence, or breach of warranty, must establish, among other things, that the defect in the product is attributable to the seller. *Wood v. Toyota Motor Corporation*, 134 Md. App. 512, 517-18, 760 A.2d 315 (quoting *Jensen v. American Motors Corp.*, 50 Md.App. 226, 234, 437 A.2d 242 (1981)), cert. denied, 362 Md. 189, 763 A.2d 735 (2000); *Loh v. Safeway Stores, Inc.*, 47 Md. App. 110 (1980); *Phipps v. General Motors Corp.*, 278 Md. 337, 363 A.2d 955 (1976). See *Tidler v. Eli Lilly & Co.*, 851 F.2d 418, 424 (D.C.Cir.1988) (applying Maryland law and refusing to adopt non-identification theories of product liability because such theories had not been recognized by Maryland courts); *Lohrmann v. Pittsburgh Corning Corp.*, 782 F.2d 1156, 1163-64 (4th Cir.1986) (verdict in favor of asbestos manufacturers affirmed when plaintiff did not demonstrate exposure to defendants' products).

The Amended Complaint should be dismissed for lack of product identification since it does not “show” that the defect in the MSS product that was used or consumed by Mrs. Trope is attributable to Alaunus. Plaintiffs’ conclusion that the defect in the MSS product that was used or consumed by Mrs. Trope is based on the assertions that NECC, Ameridose, MSM, and Alaunus “mix, compound, manufacture, test, produce, oversee, sell and/or supply” medications such as MSS, that “*NECC, Ameridose, Alaunus and MSM* sold and/or distributed chemical compounds” which were ultimately distributed to Maryland, and that Mrs. Trope was injected with a compound of MSS “which was mixed, compounded, manufactured, tested, produced, overseen and/or supplied by *NECC, Ameridose, Alaunus and MSM.*” *Pl. Compl.* at ¶¶ 14 – 17. The Amended Complaint does not contain any allegations pertaining to the identification of the manufacturer of the product such as the lot numbers of the injection vials that were distributed to Mrs. Trope's medical provider; the lot number or product code of the injection vial allegedly used to treat Mrs. Trope; the name of the manufacturer listed on the injection vial that was used to treat Mrs. Trope; the trademark or logo depicted on the labeling affixed to such injection vials; whether the product was brand name or generic; the volume of the injection vial; or whether he received an injection of preservative free formula or not. Thus, the assertions in paragraphs 14 – 17 of the Amended Complaint should be

ignored by the Court because they are not accompanied by any independent *factual allegations* which “show” that Alaunus was involved in the manufacturing and distribution of the MSS product that allegedly caused Mrs. Trope’s injury. Putting aside these conclusory assertions, the Amended Complaint fails to state a product liability claim against Alaunus under any theory of liability because it does not permit anything more than a possibility that the defect in the product used by Mrs. Trope is attributable to Alaunus. *See Patterson v. Novartis Pharmaceuticals Corp.*, 451 Fed. Appx. 495 (6th Cir. Aug. 23, 2011) (affirming dismissal for failure to state a claim because Massachusetts law requires that a plaintiff suing a manufacturer in a product-liability action be able to prove that his or her injury can be traced to that specific manufacturer and the factual allegations in the complaint only permitted the Court to infer the possibility that the plaintiff received infusions of the name-brand drug, Aredia, manufactured by Novartis, as opposed to the generic equivalent manufactured by some other manufacturer).<sup>12</sup>

**b. The Negligent Misrepresentation Claim Should be Dismissed Because It is Not Pled With Particularity as Required by Fed.R.Civ.P. 9(b).**

Rule 9(b) of the Federal Rules of Civil Procedure provides that “[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity. Malice, intent, knowledge, and other condition of mind of a person may be averred generally.” Fed. R. Civ. P. 9(b). The First Circuit has interpreted Rule 9(b) to require “specification of the time, place, and content of an alleged false representation.” *Arruda v. Sears*, 310 F.3d 13, 18-19 (1st Cir. 2002); *McGinty v. Beranger Volkswagen, Inc.*, 633 F.2d 226, 228 (1st Cir. 1980). The plaintiff must plead “the who, what, where, and when of the allegedly false or fraudulent representation.” *Alternative Sys. Concepts, Inc. v. Synopsys, Inc.*, 374 F.3d 23, 29 (1st Cir. 2004). The purpose of this requirement is to “give notice to defendants of the plaintiffs’ claim, to protect defendants whose reputation may be harmed by meritless claims of fraud, to discourage ‘strike suits,’ and to prevent the filing of suits that simply hope to uncover relevant information during discovery.” *See Doyle v. Hasbro, Inc.*, 103 F.3d 186, 194 (1st

<sup>12</sup> *See also In re Fosamax Products Liability Litigation*, 2010 WL 1654156 (S.D.N.Y. April 9, 2010) (dismissing all product liability claims, observing that statement that “Defendants, either directly or through [their] agents, apparent agents, servants, or employees, at all relevant times, designed, tested, developed, manufactured, labeled, marketed, distributed and sold Fosamax and Boniva” was conclusory since the complaint did not provide any specifics to support such a conclusion); *Peterson v. Breg*, 2010 U.S. Dist. Lexis 48985 (D. Ariz. April 29, 2010) (dismissing complaint that failed to identify which manufacturers’ products were actually used); *Johnson v. Moog, Inc.*, 2011 WL 719600 (E.D. Tex. Feb. 22, 2011) (all claims in medical device case dismissed because the pleading asserted only that unknown “defendants” committed actions and failed to state sufficient facts to identify defective product).

Cir.1996).

As an initial matter, Rule 9(b) applies to the Plaintiffs' negligent misrepresentation claim. Plaintiffs' negligent misrepresentation claim is based upon allegations of false statements purportedly made by the "Defendants" in certain "marketing" materials, including a "website," concerning the quality and safety of NECC's pharmaceuticals, which were allegedly relied on by the Plaintiffs and their physicians to the Plaintiffs' injury. *See Pl. Amend. Compl.* at ¶ 43 (stating that "*Defendants* made these statements in its *marketing*, including but not limited to its *website* in which it asserted: NECC (New England Compounding Center) is a compounding-only pharmacy dedicated to providing the highest quality compounded medications and services to patients and prescribers. NECC is USP Chapter 797 compliant. Pharmacists formulate all medications with only the highest grade chemicals in the state-of-the-art compounding facility."). Accordingly, Rule 9(b) applies because fraud lies at the core of the negligent misrepresentation claim. *See N. Am. Catholic Educ. Programming Found., Inc. v. Cardinale*, 567 F.3d 8, 15 (1st Cir. 2009) (Boudin, J.) ("[O]ne might think that negligent misrepresentation and fiduciary duty were not on their face subject to Rule 9(b), but the case law here and in other circuits reads Rule 9(b) expansively to cover associated claims where the core allegations effectively charge fraud").

The negligent misrepresentation claim should be dismissed for failing to plead the claim with particularity as required by Fed.R.Civ.P. 9(b) because the Amended Complaint does not specify the "who" or "where" or of the alleged false representations. The Amended Complaint does not specify the "who" of the allegedly false representations since the pleading "lumps" the defendants together by referring to them simply as "Defendants," and does not identify the author of the "marketing" materials or the registered owner of the domain name for the "website." *See Mills v. Polar Molecular Corp.*, 12 F.3d 1170, 1175 (2<sup>nd</sup> Cir. 1993) ("Rule 9(b) is not satisfied where the complaint vaguely attributes the alleged fraudulent statements to 'defendants'").<sup>13</sup> Additionally, the Amended Complaint fails to specify the "where" of the allegedly false representations because the pleading generally refers to certain "marketing" materials without providing any specifics as to the type, title, or date of

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<sup>13</sup> *See also Sears v. Likens*, 912 F.2d 889, 893 (7th Cir. 1990) ("a complaint that attributes misrepresentations to all defendants, lumped together for pleading purposes, generally is insufficient" to satisfy Rule 9(b)); *Vicom, Inc. v. Harbridge Merchant Services, Inc.*, 20 F.3d 771, 778 (7th Cir. 1994)(allegations stating that misrepresentations were made "at the direction, under the supervision, or with the knowledge and consent of all the defendants" were insufficient under the rules); *Brooks v. Blue Cross and Blue Shield of Florida, Inc.*, 116 F.3d 1364, 1381 (11th Cir. 1997) ("Plaintiffs have simply 'lumped together' all of the Defendants in their allegations of fraud").



such materials, and does not identify the “website” by its address on the Internet (URL). Given that the Amended Complaint does not plead the “who” or “where” of the allegedly false representations at issue, it fails to satisfy the particularity requirements of Rule 9(b) and should therefore be dismissed. *See Arruda*, 310 F.3d at 18-19; *McGinty*, 633 F.2d at 228; *Alternative Sys. Concepts, Inc.*, 374 F.3d at 29; *Doyle*, 103 F.3d at 194. *See also Foster v. American Home Products Corp.*, 29 F.3d 165, 168, 171 (4th Cir. July 14, 1994) (applying Maryland law) (name brand manufacturer not liable under negligent misrepresentation theory for injury caused by use of generic drug).<sup>14</sup>

c. **The Claim for Breach of Express Warranty Should Be Dismissed For Failure to Allege a Specific Affirmation of Fact, to Allege that the Warranty Was Part of the Basis of the Bargain.**

Actions based on a breach of express warranty are governed by Maryland Commercial Law Article 2-313, which are based primarily on the Uniform Commercial Code. Under Maryland law, in order to state a claim for breach of express warranty, the plaintiffs must properly allege: “(1) a warranty existed; (2) the product did not conform to the warranty; and (3) the breach proximately caused the injury or damage.” *Robinson v. Am. Honda Motor Co.*, 551 F.3d 218, 223 (4th Cir. 2009) (applying Maryland law). A warranty exists where the defendant made an affirmation, promise or description that relates to the goods and became part of the “basis of the bargain” for the product. *Rite Aid Corp. v. Levy-Gray*, 894 A. 2d 563, 572 - 574 (Md. 2006). Thus, to show the existence of a warranty at the pleading stage, a plaintiff must set forth allegations in the complaint that would establish that “the representation . . . form[ed] the basis of the bargain.” *Pulte Home Corp. v. Parex, Inc.*, 923 A. 2d 971, 996 (Md.App.Ct. 2007) (citing *Thomas v. Ford Motor Credit Co.*, 48 Md.App. 617, 624, 429 A.2d 277 (1981)).

The express warranty claim should be dismissed for failure to show that a warranty existed between Alaunus and Mrs. Trope. Like the negligent misrepresentation claim, the express warranty count in the Amended Complaint simply refers to the “Defendants” and their purported “marketing” materials and website.<sup>15</sup> The

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<sup>14</sup> The same result follows if this Court applies Massachusetts law. *See Kelly v. Wyeth-Ayerst Laboratories Co.*, 2005 WL 4056740, at \*2-5 (Mass. Super. 2005) (name brand manufacturer not liable under negligent misrepresentation theory for generic product); *Kelly v. Wyeth-Ayerst Laboratories Co.*, 2005 WL 4056740, at \*2-5 (Mass. Super. 2005) (name brand manufacturer not liable under negligent misrepresentation theory for generic product).

<sup>15</sup> *See Pl. Amend. Compl.* at ¶ 54 (stating that “Defendants expressly warranted the safety and quality of its products in its marketing, including but not limited to its website in which it asserted: NECC (New England Compounding Center) is a compounding-only pharmacy dedicated to providing the highest quality compounded medications and services to patients

Amended Complaint does not identify the type, name/title, author or date of the purported “marketing” materials, or the URL, name, or registered owner of the domain name of the “website.” Given that the Amended Complaint fails to plead facts showing that Alaunus was the maker of any allegedly false affirmations or promises, and that such affirmations or promises became part of the basis of a bargain between Alaunus and Mrs. Trope, Plaintiffs’ express warranty claim should be dismissed for failure to state a claim for relief. *See Pulte Home Corp.*, 923 A.2d at 996 (affirming dismissal of express warranty claim because plaintiff did not allege in amended complaint that defendant manufacturer made any written representation directly to the plaintiff that constituted an express warranty).<sup>16</sup>

**d. The Claim for Violation of Maryland’s Consumer Protection Act Should Be Dismissed Because A Prescription Drug Product is Not a “Consumer Good,” and the Amended Complaint Does Not Show that Plaintiffs Suffered Loss or Injury As a Result of Alaunus’ Conduct.**

Plaintiffs’ claims under the Maryland CPA should be dismissed because MSS is not a “consumer good” and was provided to Mrs. Trope as a medical service, and the Amended Complaint fails to plead any facts showing that Plaintiffs suffered an injury or loss as a result of Alaunus’ conduct.

To establish a violation of the Maryland’s Consumer Protection Act, Md. Code Ann., Com. Law § 13-101, et seq. (“Maryland CPA”), a plaintiff must prove that the defendant engaged in unfair and deceptive trade practices in connection with the sale or offer for sale of “consumer goods,” causing the plaintiff to suffer an actual injury or loss. Md. Code Ann., Com. Law § 13-101, et seq.; *Morris v. Osmose Wood Preserving*, 340 Md. 519, 538-539, 667 A.2d 624 (1995); *Golt v. Phillips*, 517 A.2d 328, 333 (Md. 1986) (“in determining the damages due the consumer, we must look only to his actual loss or injury caused by the unfair or deceptive trade practices”). Under the CPA, “consumer goods” are those good “which are primarily for personal, household, family, or

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and prescribers. NECC is USP Chapter 797 compliant. Pharmacists formulate all medications with only the highest grade chemicals in the state-of-the-art compounding facility.”).

<sup>16</sup> See also *Johnson v. Brown & Williamson Tobacco Corp.*, 122 F. Supp. 2d 194, 206 (D. Mass. 2000) (dismissing express warranty claim for failure to sufficiently plead facts showing the existence of an express warranty where plaintiff claimed that the defendant extended an express warranty to the Plaintiff through its “advertising, marketing and other efforts,” but offered no specific affirmation of fact or promise, nor any particular description, sample or model that might give rise to such a warranty); *Gelber v. Stryker Corp.*, 752 F. Supp.2d 328 (S.D.N.Y. 2010) (express warranty claim dismissed due to failure to plead the warranty or how it was breached); See *Delaney v. Stryker Orthopaedics*, 2009 WL 564243 (D.N.J. 2009) (express warranty claim dismissed under *Twombly-Iqbal* due to failure to specify the language that constituted the warranty); *Horsmon v. Zimmer Holdings, Inc.*, 2011 WL 5509420 (W.D. Pa. Nov. 10, 2011) (express warranty claim dismissed due to failure to plead the specifics regarding the alleged warranty or how it became part of the basis of the bargain).

agricultural purposes.” § 13-101(d). The section authorizing a private action for damages, § 13-408(d), also includes an exclusion that: “notwithstanding any other provision of this section, a person may not bring an action under this section to recover for injuries sustained as a result of the professional services provided by a health care provider, as defined in § 3-2A-01 of the Courts Article.”

The Maryland District Court recently dismissed a similar claim under the Maryland CPA in *Pease v. Abbott Lab., Inc.*, Slip. Op. No.: JKB-12-1844, 2013 WL 174478 (D. Md. Jan. 16, 2013) (Bredar, J.) for three reasons. In support of the Maryland CPA claim, Plaintiff alleged that

“Abbott engaged in deceptive practices by engaging in false and misleading advertising which omitted material facts with the intent that Mrs. Pease and consumers rely upon these representations as complete and accurate, including indicating that Humira was safe for use concomitantly with methotrexate and/or corticosteroids, and omitting that Humira had reportedly caused central nervous system problem [sic] due to autoantibodies or demyelination, and encephalitis and/or meningitis in patients . . .” *Id.*, \* 2.

The *Pease* court held that the prescription drug was not a “consumer good” because “the Humira used by Mrs. Pease was selected by her physician and prescribed for her, not as a consumer good, but as part of her course of medical treatment.” *Id.*, at \* 2, citing *Hogan v. Md. State Dental Ass’n*, 843 A.2d 902, 906 (Md. Ct. Spec. App. 2004) (dental fillings are not consumer goods under the Maryland CPA because they are not purchased by consumers as a good but are selected and used by a practitioner as part of a professional service). The *Pease* court also found that the Maryland CPA claim fell within the exclusion in § 13-408(d) because the professional services provided by the plaintiff’s physician included his prescribing certain medicines for her, and her injuries were allegedly sustained as a result of her using one of those medicines. *Pease*, 2013 WL 174478, \* 2 – 3. Moreover, the *Pease* court found that the complaint failed to plead sufficient facts to show that the plaintiff suffered an actual injury as a result of the alleged unfair and/or deceptive acts or practices of the manufacturer. *Id.*, \* 2.

The Tropes’ claim under the CPA should be dismissed for the same three reasons that the CPA claim was dismissed in *Pease*. The CPA claim is based on the same allegations that form the basis of the Plaintiffs’ negligent misrepresentation and express warranty claims – e.g. that Defendants made false representations and warranties about their pharmaceutical products in their “marketing” materials and “website” which caused injury

to the Plaintiffs.<sup>17</sup> The claim fails because MSS is not a “consumer good” since her physician or other medical provider at Sinai Hospital selected the drug and prescribed it for her, not as a consumer good, but as part of her course of medical treatment. *See Hogan*, 843 A.2d at 96; *Pease*, 2013 WL 174478, \* 2. Additionally, the CPA claim falls within the exclusion in § 13–408(d) and is therefore barred because the professional services provided by Mrs. Trope’s medical provider included his or her prescribing certain medicines for the Plaintiff, and her injuries were allegedly sustained as a result of her using that medicine. *See Hogan*, 843 A.2d at 96; *Pease*, 2013 WL 174478, \* 2 - 3. Furthermore, the CPA claim fails for lack of causation because the Amended Complaint does not contain any factual allegations, as opposed to conclusory assertions, showing that *Alaunus* was in any way involved in the promotion, marketing and warning of the MSS product that was used by Mrs. Trope or that *Alaunus* made any false statements which were relied on by Mrs. Trope or her physician to her injury. *See Pease*, 2013 WL 174478, \* 2. *See also Foster, supra*, 29 F.3d at 171 - 172 (dismissing negligent misrepresentation claim for lack of duty and causation because plaintiff was injured by a product that defendant did not manufacture).

e. **The Claim for Violation of M.G.L. c. 93A Should Be Dismissed Because the Amended Complaint Does Not Show that Alaunus Committed Any Unfair or Deceptive Act or that Plaintiffs Suffered Injury As a Result of Such Conduct.**

The Plaintiffs’ claim under the Massachusetts Consumer Protection Act, Mass. Gen. Laws c. 93A, § 9 (“Chapter 93A”)<sup>18</sup>, which is based on the allegation that *Alaunus* committed “unfair and deceptive practices in the promotion, marketing and warning” of MSS, *Pl. Compl.*, at ¶¶ 76 – 77, should be dismissed for substantially the same reasons that the Maryland CPA claim should be dismissed. As established above, the Amended Complaint fails to plead facts indicating that *Alaunus* was in any way involved in the manufacture, marketing, advertising, promotion, sale, or distribution of the MSS product that was used by Mrs. Trope. Consequently, the Plaintiffs’ Chapter 93A claim against *Alaunus* should be dismissed because the Amended Complaint does not show that

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<sup>17</sup> *Pl. Compl.* at ¶¶ 69 – 70 (stating that “Defendants engaged in unfair and deceptive practices in the promotion, marketing and warning of its product” by “omit[ing] material facts and expressly stat[ing] untrue and false information with the intent that Mrs. Trope, physicians, and consumers rely upon these representations as complete and accurate, including indicating: a. NECC was a compounding only pharmacy; b. NECC provided the highest quality compounded medications; c. that Pharmacists formulate all medications with only the highest grade chemicals; d. that NECC used a state of the art compounding facility; and, f. that NECC’s product was reasonably safe.”).

<sup>18</sup> To state a claim under Section 9 of M.G.L. c. 93A, a plaintiff must allege and prove that the defendant committed a deceptive act or practice, that the consumer suffered an actual injury or loss, and that a causal connection exists between the business entity’s deceptive act or practice and the consumer’s injury. *Hershenow v. Enterprise Rent -A-Car, Inc.*, 445 Mass. 790, 797 - 798 (2006).

*Alaunus* committed an unfair or deceptive act or practice or that Plaintiffs suffered a loss or injury as a result of any such conduct. See *Macoviak v. Chase Home Mortg. Corp.*, 40 Mass.App.Ct. 755, 760 (1996) (affirming dismissal of plaintiff's Chapter 93A claim because it was "solely based upon his underlying claim for common law fraud" on which the court had also granted summary judgment); *Ford v. Carey*, 77 Mass.App.Ct. 1106 (2010) (lower court's award of statutory damages and attorneys' fees to plaintiff under Chapter 93A was reversible error because the plaintiff suffered no loss of money, loss of property, or personal injury as a result of the defendant's unfair or deceptive act).<sup>19</sup>

**f. The Loss of Consortium Claim Should Be Dismissed Because it is Derivative of the Failed Tort Claims Against Alaunus.**

Loss of consortium, an action for damages to the marital relationship, is a derivative claim which depends for its sustenance upon a viable tort claim of the spouse. *Daley v. United Servs. Automobile Ass'n*, 541 A.2d 632, 635 n.3 (Md. 1988) ("loss of consortium is a claim. . . which can be asserted only in a joint action"); *Georges v. Duncan*, 295 A.2d 809 (Md. App. 1972) (A loss-of-consortium action is "derivative"). For the reasons previously stated, Mrs. Trope has no right to recover against Alaunus under any of the theories asserted in the Amended Complaint. Given that the Amended Complaint fails to state a claim on behalf of Mrs. Trope against Alaunus, Mr. Trope's loss of consortium claim fails as a matter of law since it is derivative of his spouse's failed common law and statutory claims against Alaunus.

**g. The Punitive Damages Claim Should Be Dismissed Because the Amended Complaint Does Not Contain Any Facts Showing that Alaunus Acted with Actual Malice, and it is Derivative of the Failed Tort Claims Against Alaunus.**

As established above, the Amended Complaint fails to show that Alaunus had any involvement whatsoever in the manufacture or sale of MSS, let alone allege, in detail, any *factual allegations* that, if proven true, would support the conclusion that Alaunus acted with 'actual malice.' On this basis alone, the punitive damages claim should be dismissed. See *Scott v. Jenkins*, 345 Md. 21, 37 (1997) ("in order to properly plead a claim for punitive damages, a plaintiff must make a specific demand for that relief in addition to a claim for

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<sup>19</sup> See also *Wasylyow v. Glock, Inc.*, 975 F.Supp. 370, 382 (D.Mass.1996) (dismissing Chapter 93A claim because plaintiff "advanced no facts in support of his Chapter 93A claim, other than the facts underlying his failed warranty and negligence claims"); *Chapman v. Katz*, 65 Mass.App.Ct. 826 (2006) (holding that award of attorneys' fees under Chapter 93A was improper because plaintiff suffered no loss as a result of defendant's deceptive act).

damages generally, as well as allege, in detail, facts that, if proven true, would support the conclusion that the act complained of was done with ‘actual malice.’ Nothing less will suffice.”). Moreover, the punitive damages claim should be dismissed because it is an element of damages in and wholly derivative of Plaintiffs’ failed tort claims against Alaunus. *See Havlik v. Johnson & Wales Univ.*, 509 F.3d 25, 34 (1st Cir.2007) (“punitive damages are not a separate cause of action but, rather, an element of damages in, and thus wholly derivative of, the plaintiff’s defamation claim”); *Pan Am Systems, Inc. v. Hardenbergh*, 871 F.Supp.2d 6, 18 (D. Me. 2012) (because the Plaintiffs’ underlying causes of action are insufficient to state a claim under Rule 12(b)(6), the Plaintiffs’ claim for punitive damages must also be dismissed).

## V. CONCLUSION

Plaintiffs’ Amended Complaint fails to state a claim for relief against Alaunus for many reasons. The Amended Complaint does not plead sufficient facts to show that Alaunus is jointly or vicariously liable for NECC’s alleged tortious conduct under an alter-ego liability theory, impermissibly “lumps” the defendants together, and does not identify Alaunus as the manufacturer or seller of any product, let alone MSS. The negligent misrepresentation and express warranty claims fail because the Amended Complaint does not show that Alaunus made any representations to Mrs. Trope or that they became part of the basis of the bargain. The claims under Maryland’s and Massachusetts’ Consumer Protection Act fail because MSS is not a “consumer good” within the meaning of Maryland CPA, and the Amended Complaint does not show that Alaunus committed any unfair or deceptive act or practice, or that Mrs. Trope suffered an injury or loss as a result of any such conduct. Mr. Trope’s claim for “damage to the marital relationship” fails because that claim is derived from his spouse’s failed claims against Alaunus. Given that all of the underlying tort claims against Alaunus are subject to dismissal and that the Amended Complaint does not support a plausible inference that Alaunus acted with “actual malice,” the claim for punitive damages should be dismissed. For these reasons, the Amended Complaint should be dismissed as to Alaunus, pursuant to Fed.R.Civ.P. 12(b)(6).<sup>20</sup>

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<sup>20</sup> Whereas the Complaint woefully fails to state a claim for relief against Alaunus and discovery in these multi-district proceedings will be massive, Plaintiffs are not entitled to conduct any discovery to cure the defects in their pleading. *See Twombly*, 127 S. Ct. at 1966 (rejecting arguments that a plaintiff should be permitted to proceed with discovery and that case management techniques may be used by defendants to weed out baseless claims in an anti-trust case ruling that one of the main goals of the plausibility standard is the avoidance of unnecessary discovery and discovery would be massive since the Plaintiff represents a putative class of at least 90 percent of all subscribers to local telephone or high-speed Internet service in the continental United States in an action against America’s largest telecommunications firms, Supreme Court); *Dura Pharmaceuticals, Inc. v. Broudo*, 125 S.Ct. 1627 (2005) (“something beyond the mere possibility of loss causation must be



Dated: April 22, 2013

Respectfully Submitted,  
Alaunus Pharmaceutical, LLC,  
By its Attorney,

*/s/ Ryan Ciporkin*

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**CERTIFICATE OF SERVICE**

This is to certify that a copy of the foregoing has been filed with the Clerk of the Court on April 22, 2013 using the CM/ECF system which sent notification of this filing to all ECF registered counsel of record via e-mail generated by the Court's ECF system.

*/s/ Ryan Ciporkin*

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